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# NOTICE OF ALLOWANCE AND FEE(S) DUE

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06/02/2010

SUGHRUE MION, PLLC 2100 PENNSYLVANIA AVENUE, N.W. SUITE 800 WASHINGTON, DC 20037 EXAMINER

JONES JR., ROBERT STOCKTON

ART UNIT PAPER NUMBER

1796

DATE MAILED: 06/02/2010

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/590,959	03/12/2007	Doo Sung Lee	Q96860	5634

TITLE OF INVENTION: PH AND TEMPERATURE SENSITIVE HYDROGELS

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	\$755	\$300	\$0	\$1055	09/02/2010

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

#### HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

### PART B - FEE(S) TRANSMITTAL

### Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE

Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450

or <u>Fax</u> (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where ar in m

appropriate. All further correspondence including the Patent, advance orders and notification indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new continuous maintenance fee notifications.  CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)  23373 7590 06/02/2010  SUGHRUE MION, PLLC 2100 PENNSYLVANIA AVENUE, N.W. SUITE 800				on of maintenance fees will be mailed to the current correspondence address as a correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.  Certificate of Mailing or Transmission  I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.			
			_				(Signature)
			L				(Date)
APPLICATION NO.	FILING DATE		FIRST NAMED INVENTO	)R	ATTO	RNEY DOCKET NO.	CONFIRMATION NO.
10/590,959	03/12/2007		Doo Sung Lee			Q96860	5634
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nonprovisional	YES	\$755	\$300	\$0	E FEE	\$1055	09/02/2010
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	ERT STOCKTON	1796	525-408000	_			
CFR 1.363).  Change of corresp Address form PTO/S.  "Fee Address" ind PTO/SB/47; Rev 03-(Number is required.  3. ASSIGNEE NAME A PLEASE NOTE: Un	ND RESIDENCE DATA less an assignee is ident th in 37 CFR 3.11. Com	unge of Correspondence "Indication form ned. Use of a Customer A TO BE PRINTED ON	data will appear on the T a substitute for filing a (B) RESIDENCE: (CIT	to 3 registered pater tively, gle firm (having as a r agent) and the nan torneys or agents. If he printed.  Type)  patent. If an assign n assignment.  Ty and STATE OR 6	nt attorn a member sof up no nam	er a 2	cument has been filed for
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☐ Issue Fee ☐ Publication Fee (No small entity discount permitted) ☐ Advance Order - # of Copies			4b. Payment of Fee(s): (Please first reapply any previously paid issue fee shown above)  ☐ A check is enclosed. ☐ Payment by credit card. Form PTO-2038 is attached. ☐ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number (enclose an extra copy of this form).				
5. Change in Entity Sta  a. Applicant claim	n <b>us</b> (from status indicate is SMALL ENTITY stati	,	☐ b. Applicant is no lo	onger claiming SMA	LL ENT	TTY status. See 37 CF	R 1.27(g)(2).
NOTE: The Issue Fee an interest as shown by the	nd Publication Fee (if req records of the United Sta	uired) will not be accepte ites Patent and Trademarl	ed from anyone other thank Office.	the applicant; a reg	istered a	ttorney or agent; or the	assignee or other party in
Authorized Signature				Date			
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This collection of inform an application. Confiden submitting the complete this form and/or suggest Box 1450, Alexandria, V Alexandria, Virginia 223	itiality is governed by 35 dapplication form to the ions for reducing this bu /irginia 22313-1450. DC	CFR 1.311. The informati JU.S.C. 122 and 37 CFR E USPTO. Time will vary rden, should be sent to the O NOT SEND FEES OR	on is required to obtain on 1.14. This collection is on the included of the included of the collection of the completed of th	r retain a benefit by estimated to take 12 lividual case. Any c cer, U.S. Patent and TO THIS ADDRES	the publ minutes omments Tradem S. SENI	ic which is to file (and to complete, including s on the amount of tim tark Office, U.S. Depa O TO: Commissioner fo	by the USPTO to process); gathering, preparing, and e you require to complete the threat of Commerce, P.O. or Patents, P.O. Box 1450,

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10/590,959	03/12/2007	Doo Sung Lee	Q96860 5634		
23373 7:	590 06/02/2010		EXAMINER		
SUGHRUE MION, PLLC 2100 PENNSYLVANIA AVENUE, N.W.			JONES JR., ROBERT STOCKTON		
			ART UNIT	PAPER NUMBER	
SUITE 800 WASHINGTON, DC 20037			1796 DATE MAILED: 06/02/201	0	

### **Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)**

(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 391 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 391 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

	Application No.	Applicant(s)	
	''		
Notice of Allowability	10/590,959 <b>Examiner</b>	LEE ET AL. Art Unit	
,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	Lammer	Artonic	
	ROBERT JONES JR.	1796	
The MAILING DATE of this communication appeal claims being allowable, PROSECUTION ON THE MERITS IS herewith (or previously mailed), a Notice of Allowance (PTOL-85) NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT R of the Office or upon petition by the applicant. See 37 CFR 1.313	(OR REMAINS) CLOSED in or other appropriate communication is selection in section in the communication in the comm	n this application. If not included unication will be mailed in due cou	rse. <b>THIS</b>
1. X This communication is responsive to the Request for Cont	tinued Examination dated 27	<u>April 2010</u> .	
2. ☑ The allowed claim(s) is/are <u>1-6 and 8-16</u> .			
<ul> <li>3.  Acknowledgment is made of a claim for foreign priority u</li> <li>a)  All b)  Some* c)  None of the:</li> <li>1.  Certified copies of the priority documents have</li> </ul>		or (f).	
2. Certified copies of the priority documents have		on No	
3. Copies of the certified copies of the priority do	• •		from the
International Bureau (PCT Rule 17.2(a)).		3	
* Certified copies not received:			
Applicant has THREE MONTHS FROM THE "MAILING DATE" noted below. Failure to timely comply will result in ABANDONN THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.		a reply complying with the require	ements
4. A SUBSTITUTE OATH OR DECLARATION must be subm INFORMAL PATENT APPLICATION (PTO-152) which giv			CE OF
5. CORRECTED DRAWINGS ( as "replacement sheets") mus	st be submitted.		
(a) ☐ including changes required by the Notice of Draftspers	son's Patent Drawing Review	v ( PTO-948) attached	
1) 🔲 hereto or 2) 🔲 to Paper No./Mail Date	<u>.</u>		
<ul><li>(b) ☐ including changes required by the attached Examiner' Paper No./Mail Date</li></ul>	's Amendment / Comment o	in the Office action of	
Identifying indicia such as the application number (see 37 CFR 1 each sheet. Replacement sheet(s) should be labeled as such in the			k) of
<ol> <li>DEPOSIT OF and/or INFORMATION about the depo- attached Examiner's comment regarding REQUIREMENT</li> </ol>			the the
Attachment(s)	E   Notice of In	formal Datant Application	
1. Notice of References Cited (PTO-892)		formal Patent Application	
<ol> <li>Notice of Draftperson's Patent Drawing Review (PTO-948)</li> <li>Information Disclosure Statements (PTO/SB/08),</li> </ol>	Paper No.	ummary (PTO-413), /Mail Date Amendment/Comment	
Paper No./Mail Date			
<ol> <li>Examiner's Comment Regarding Requirement for Deposit of Biological Material</li> </ol>		Statement of Reasons for Allowar	nce
/D. 1./	9. ☐ Other	_•	
/R. J./ Examiner, Art Unit 1796	/David Wu/	tont Evaminar Art Unit 1700	
Examinot, Art Offic 1750	Supervisory Pa	tent Examiner, Art Unit 1796	

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#### **REASONS FOR ALLOWANCE**

1. The following is an examiner's statement of reasons for allowance:

- 2. The amendment to Claim 1 requires a block copolymer which forms a hydrogel by sol-gel transition in accordance with a change in temperature and pH. As illustrated by the Applicant's arguments, Han's copolymers undergo a transition between micelle aggregation and segregation in response to a change in pH, rather than a sol-gel transition. This is shown, for example, in the figures on page 8 of the Applicant's remarks, and is more clearly illustrated by the figure which appears on page 9. The phenomenon is also described on page 58, col. 1, paragraph 2 of Han.
- 3. Additionally, the cited article to Shim et al included with the Applicant's remarks provides evidence that Huang's copolymers do not undergo a sol-gel transition in response to changes in pH and temperature as per the instant claims. See, for example, p. 1939, Figure 5 of Shim, also reproduced on page 10 of the Applicant's remarks. Shim works with copolymers identical to those taught by Huang.
- 4. Thus, it is evident that Han and Huang exhibit far different characteristics in response to changes in pH and temperature. Han's copolymers are specifically designed to exhibit a desired effect based on small changes in pH that occur when transitioning from normal tissue (pH=7.4) and tumors (pH=7.0). Based on the results presented by each reference, it is clear that modification of Han in view of Huang would cause Han's copolymers to cease functioning as intended. Furthermore, based on the results presented by both references and also on the results presented by Shim et al,

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neither reference provides any indication or expectation that modification of Han in view of Huang would result in a block copolymer which forms a hydrogel by sol-gel transition in accordance with a change in both temperature and pH.

- 5. In light of the Applicant's arguments, Claim 1 is allowable over the prior art to Han and Huang. The remaining claims 2-6 and 8-16 each require the block copolymer of Claim 1, and are therefore also allowable.
- 6. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

#### Conclusion

- 7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROBERT JONES JR. whose telephone number is (571)270-7733. The examiner can normally be reached on Monday Thursday, 9 AM 5 PM.
- 8. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Wu can be reached on 571-272-1114. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.
- 9. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

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published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information

system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

RSJ

/David Wu/ Supervisory Patent Examiner, Art Unit 1796